

REMARKS

Claims 15-20 are new. Claims 1-20 are pending. Favorable consideration is respectfully requested.

At the outset, Applicants thank Examiner Coleman for the helpful suggestions during the courteous discussion of the present application which is summarized and expanded upon below. Further, Applicants thank Examiner Coleman for indicating that the above amendment, combined with the remarks below, would further favorable prosecution of the present invention.

The objection to Claims 1, 2, and 4-14 for an improper Markush Group is believed to be obviated by the above amendment. More specifically, Applicants have amended the claims to remove the non-elected subject matter. Accordingly, withdrawal of this ground of objection is respectfully requested.

The objection to the Amendment filed July 10, 2002, is believed to be obviated by the above amendment. More specifically, the specification has been amended to remove the subject matter deemed "new" by the Examiner. Accordingly, withdrawal of this ground of objection is respectfully requested.

The rejection to the Claims 4 and 5 under 35 U.S.C. § 112, first paragraph, is believed to be obviated by the above amendment. More specifically, the Claim 4 has been amended to remove the subject matter deemed "new" by the Examiner. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection to the Claims 9-14 under 35 U.S.C. § 112, first paragraph, is believed to be obviated by the above amendment. The use and functional claims have been rewritten to be in proper method of use claim format, including a positive active step. Further, all claims have been amended to remove "preventing" and derivations thereof, as well as "inhibiting"

and derivations thereof. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection to the Claims 1-14 under 35 U.S.C. § 112, second paragraph, is believed to be obviated by the above amendment. More specifically, the Claim 3 has been amended to replace "derivative" with --compound--. Further, Claims 9-11 and 13 have been amended to be drawn to a pharmaceutical composition. Finally, Claim 12 has been amended to recite a method of use which with an active positive step which is drawn to a method of arresting, alleviating, or reducing the production of IgE antibody in a subject. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The provisional obviousness-type, non-statutory double-patenting rejection to the Claims 1-14 over US Application Number 09/893,698 (US'698) is traversed below.

The claimed compounds are very different than those disclosed by US Application No. 09/893,698 (US'698) for the following reasons. First, the claimed compounds contain a bridging group, X, that is bonded to the carbon at the 5-position and the claimed substituents, A, are at the 2-position, while those compounds disclosed by US'698 do not. Further, providing substitutions at positions para and meta to the nitrogen atom of the pyridyl are impacted by the electronegativity of the pyridyl nitrogen during chemical synthesis and reactions. Therefore, the claimed compounds are not homologs of those compounds disclosed by US'698, much less structural isomers.

In light of the above, the compounds of US'698 and claimed compounds not even homologs of each other. The Federal Circuit has defined the parameters that may be considered in determining the proper use of chemical structure as the basis for obviousness rejections under 35 U.S.C. § 103 in *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992). The court cited the following examples of relationships that have given rise to a *prima facie* case of obviousness, which in turn is the standard for obviousness-type double patenting:

triorthoesters and tetraorthoesters;
stereoisomers;
adjacent homologs and structural isomers; and
acid and ethyl ester (*Id.*, at 1943).

In the present case, there exists no motivation to modify the compounds disclosed by US'698 to contain any of the claimed substituents of the claimed compounds because US'698 is silent in this regard and because the relationship between the claimed compounds and those disclosed by US'698 fail to satisfy any of the above-mentioned relationships to be defined as homologs by the Federal Circuit.

In light of the above, it appears as if the Office is relying on the Applicants disclosure to supply motivation to modify compounds disclosed by US'698 to have the claimed substituents in order to arrive at the claimed compounds. However, this simply can not be possible due the nature of the claimed bridging group, X, that is bonded to the carbon at the 5-position and the claimed substituents, A, are at the 2-position. Moreover, this is clearly improper according to a recent decision by the U.S. Federal Courts in *In re Lee* (61 USPQ2d 1430). The *Lee Court* indicated that the Office must provide specific motivation, hint, or suggestion, found in the references relied upon to support a *prima facie* case of obviousness. In the present case, the Office appears to rely on the present specification for motivation, which is clearly forbidden according to the *Lee Court*. In light of this decision, Applicants respectfully request the Office not to use the present specification to find motivation that is not present in any of the disparate disclosure of the reference discussed herein. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Application No. 09/893,680
Reply to Office Action of

Applicants respectfully submit that the present application is now in condition for allowance. Early notice to this effect is respectfully requested. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact the undersigned by telephone.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



22850

Tel: (703) 413-3000
Fax: (703) 413 -2220

A handwritten signature in black ink, appearing to read 'Norman F. Oblon', written over a horizontal line.

Norman F. Oblon
Attorney of Record
Registration No. 24,618

Thomas W. Barnes
Registration No. 52,595

I:\ATTY\TWB\208671US-AM.DOC

docket no: 208671US0

Marked-Up Copy

Serial No: 09/893,680

Amendment Filed on:
HEREWITH

IN THE SPECIFICATION

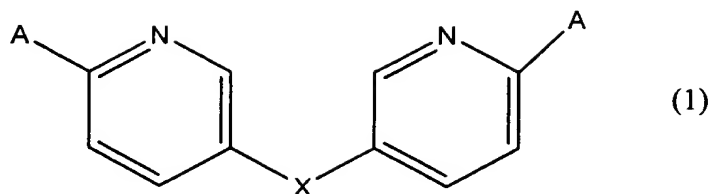
Please delete the paragraph bridging pages 4 and 5 in favor of the following new paragraph as follows:

-- In formula (1), the aromatic hydrocarbon group represented by A is preferably a group which has 6 to 14 carbon atoms, with a phenyl or naphthyl group being more preferred and a phenyl group being particularly preferred. These groups may contain 1 to 3 substituents. Suitable examples of such substituents include lower alkyl groups, lower alkoxy groups, halogeno(lower [alkoxy] alkyl) groups, lower alkoxy(lower [alkoxy] alkyl) groups, hydroxy(lower [alkoxy] alkyl) groups, carboxyl group, (lower alkoxy)carbonyl groups, unsubstituted or (lower alkyl)- and/or (lower alkoxy)-substituted carbamoyl groups, lower alkanoyl groups, formyl group, lower alkanoyloxy groups, halogen atoms, hydroxyl group, cyano, (lower alkyl)thio groups, amino group, mono- or di-(lower alkyl)amino groups, (lower alkyl)sulfonylamino groups, pyrrolidinyl groups, and alkylenedioxy groups. --

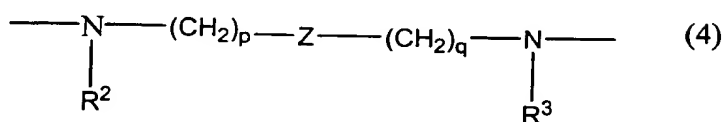
IN THE CLAIMS

Please amend the claims as follows.

--1. (Amended): A bis(2-aryl-5-pyridyl) compound having formula (1) or a salt thereof;



wherein A is a substituted or unsubstituted aromatic hydrocarbon group, and X is [a substituent having one of the following formulas (2) to] formula (4):



wherein, [in formula (2), R¹ is a hydrogen atom or a di(lower alkyl)amino(lower alkyl) group, and m is an integer of 1 or 2; in formula (3), Y¹ and Y² each is a nitrogen atom or a CH group, and n is 0 or an integer of 1 to 6;] in formula (4), R² and R³ each is a hydrogen atom or a lower alkyl group, Z represents a single bond, a substituted methylene group, a substituted imino group, an oxygen atom or a cycloalkylene group, and p and q each is 0 or an integer of 1 to 6.

3. (Amended): The bis(2-aryl-5-pyridyl) [derivative] compound or a salt thereof according to Claim 1, wherein, in formula (1), X is a group represented by formula (4).

4. (Twice Amended) The bis(2-aryl-5-pyridyl) compound or a salt thereof according to Claim 1, wherein said aromatic hydrocarbon substituent is substituted by 1 to 3 substituents selected from the group consisting of lower alkyl groups, lower alkoxy groups, halogeno(lower [alkoxy] alkyl) groups, lower alkoxy(lower [alkoxy] alkyl) groups, hydroxy(lower [alkoxy] alkyl) groups, carboxyl group, (lower alkoxy)carbonyl groups,

unsubstituted or (lower alkyl)- and/or (lower alkoxy)-substituted carbamoyl groups, lower alkanoyl groups, formyl group, lower alkanoyloxy groups, halogen atoms, hydroxyl group, cyano, (lower alkyl)thio groups, amino group, mono- or di-(lower alkyl)amino groups, (lower alkyl)sulfonylamino groups, pyrrolidinyl groups, and alkylenedioxy groups.

9. (Amended): A [medicinal] pharmaceutical composition comprising, as an active ingredient, an effective amount of a bis(2-aryl-5-pyridyl) compound or a salt thereof according to Claim 1.

10. (Amended): [The medicinal composition according to Claim 9, which is effective in the prevention or therapeutic treatment of an] A method of treating, arresting, alleviating, or reducing allergic immune disease in a subject, comprising administering the pharmaceutical composition according to Claim 9 to a subject.

11. (Amended): The [medicinal composition] method according to Claim 10, wherein said allergic immune disease is at least one member selected from the group consisting of asthma, atopic dermatitis, allergic rhinitis, inflammatory bowel disease, contact dermatitis [or] and an allergic ophthalmopathy.

12. (Amended): [An IgE antibody production inhibitor which is] A method of arresting, alleviating, or reducing the production of IgE antibody in a subject comprising, administering [a] the bis(2-aryl-5-pyridyl) compound or a salt thereof according to Claim 1 to a subject.

13. (Amended): A [medicinal] pharmaceutical composition, comprising: a bis(2-aryl-5-pyridyl) compound or a salt thereof according to Claim 1 and a pharmacologically acceptable carrier.

14. (Amended): A method of treating or alleviating a subject suffering from an allergic immune disease, which comprises:

administering an effective amount of a bis(2-aryl-5-pyridyl) compound or a salt thereof according to Claim 1 to said subject.--

--Claims 15-20 are added.--